REMARKS

Claims 1 through 11 and new Claims 12 and 13 are pending in the application.

Claims 10 and 11 have been amended to correct typographical errors.

Claims 12 and 13 have been added to complete the record for examination and highlight advantageous embodiments of the invention.

Claim 12 is directed to advantageous processes in which the deprotecting step c) is performed in an aqueous medium with hydrochloric acid at a temperature of between 90 and 95 °C. Support for Claim 12 can be found in the Application-as-filed, for example on Page 5, lines 8 through 11.

Claim 13 is directed to advantageous processes in which the deprotecting step c) is performed at a pH ranging between 0 and 2. Support for Claim 13 can be found in the Application-as-filed, for example on Page 5, lines 8 through 11.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

The Claimed Invention is Patentable
in Light of the Art of Record

Claims 1 through 11 stand rejected over United States Patent Application Publication No. 2007/0032647 ("US 647") to Parenky et al.

Applicants respectfully note that US 647 does not constitute prior art against the above-referenced application. US 647 indicates on its face that it has a 35 USC § 371 date of April 20, 2006. The present application is entitled to a priority date of March 9, 2004, as indicated by the PTO PAIR system. Consequently, the requirements of paragraphs (1), (2) and (4) of section 371 (c) were not fulfilled by US 647 prior to the instant invention, and US 647 thus does not constitute prior art.

Out of an abundance of caution; however, it may be helpful to briefly discuss the invention, particularly advantageous embodiments thereof.

Applicants respectfully reiterate that oxcarbazepine is a known anticonvulsivant agent. Oxcarbazepine is generally produced by either carbamoylation with cyanates or by chlorocarbonylation followed by ammonolysis and final hydrolysis (also referred to as deprotection). Conventional processes by which to perform the chlororcarbonylation step to date have incorporated either phosgene or diphosgene.

Altogether unexpectedly, Applicants have found that triphosgene may be used to form oxcarbazepine with greatly improved overall yields in comparison to oxcarbazepine produced using either phosgene or diphosgene, as recited in the claimed invention.

Applicants have further determined that the deprotecting step within the oxcarbazepine process may beneficially be performed at a low pH, such as at a pH of about 1, as recited in Claim 7.

In particularly advantageous embodiments, the deprotecting step is performed in an aqueous medium with hydrochloric acid at a temperature of between 90 and 95 °C, as recited in newly added Claim 12.

In expedient aspects of such embodiments, the deprotecting step is performed at a pH ranging between 0 and 2, as recited in newly added Claim 13.

Applicants respectfully reiterate that US 647 does not constitute prior art against the claimed invention. Nevertheless, solely out of an abundance of caution, Applicants respectfully submit that US 647 does not teach or suggest the claimed invention, including the advantageous embodiment of Claims 7, 12 and 13.

US 647 expressly notes that conversion processes using "strong mineral acids" lead to "degradation of oxcarbazepine." [0008]. US 647 then goes on to teach that one of the objects of its methods is the use of "mild reagents" such as Lewis acids, to effect conversion. [0014]. US 647 specifically teaches conversion in a Lewis acid at a temperature of only up to 80 °C. [0022]. Suitable Lewis acids include aluminum chloride and the like. [0028]. Exemplary solvents include chlorinated aliphatic hydrocarbons, such as methylene dichloride. [0027].

US 647, requiring "mild reagents," does not teach or suggest advantageous embodiments in which the deprotecting step is at a pH of about 1, as recited in Claim 7 as-amended.

And US 647 most certainly does not teach or suggest advantageous processes in which the deprotecting step is performed in an aqueous medium with hydrochloric acid at a temperature of between 90 and 95 °C, as recited in newly added Claim 12. Applicants respectfully submit that US 647 instead teaches away from such embodiments by instead requiring a mild reagent, such as a Lewis acid.

Applicants further respectfully submit that the advantageous use of hydrochloric acid provides a significantly reduced cost and a product having a very high purity. In that regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 6, line 20 through Page 7, line 10, Example 2, in which the HPLC purity of oxcarbazepine formed according to the inventive methods is higher than 99 %. Applicants additionally respectfully note that, not only is hydrochloric acid much cheaper than Lewis acids, but it is also much more easily removed from

the final product. For example, it can removed from the reaction cake simply by washing with water, as further disclosed in the Application-as-filed on Page 6, lines 28 through 30, Example 2.

US 647 further fails to teach or suggest such advantageous processes in which the deprotecting step is performed at a pH ranging between 0 and 2, as recited in newly added Claim 13.

Accordingly, Applicants respectfully submit that US 647 does not teach or suggest the claimed invention. Applicants further respectfully reiterate that US 647 does not even constitute prior art against the instant invention.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 13 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office PAIR Webpage via the electronic filing system in accordance with 37 CFR § 1.6(a)(4) on April 1, 2010.

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